

Neonatal Vitamin K Refusal and Nonimmunization

AUTHORS: Vanita Sahni, MHS^a, Florence Y. Lai, MPhil,^a and Shannon E. MacDonald, PhD^{b,c}

^aAlberta Health Surveillance and Assessment, Edmonton, Alberta, Canada; ^bDepartment of Pediatrics, University of Calgary, Calgary, Alberta, Canada; and ^cFaculty of Nursing, University of Alberta, Edmonton, Alberta, Canada

KEY WORDS

vitamin K, immunization, health education

ABBREVIATIONS

CI—confidence interval

DTaP-IPV-Hib—diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type b vaccine

IM—intramuscular

MMR—measles, mumps, and rubella vaccine

MMWR—*Morbidity and Mortality Weekly Report*

NOB—notice of birth

VKDB—vitamin K deficiency bleeding

Ms Sahni conceptualized and designed the study and drafted the initial manuscript; Ms Lai conceptualized and designed the study, carried out the analysis, and reviewed and revised the manuscript; Dr MacDonald conceptualized and designed the study and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

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Address correspondence to Shannon MacDonald, PhD, Department of Pediatrics, University of Calgary, 2888 Shaganappi Trail NW, Calgary, Alberta, T3B 6A8, Canada. E-mail: smacdon@ualberta.ca

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WHAT'S KNOWN ON THIS SUBJECT: Vitamin K prophylaxis at birth is an effective intervention for preventing vitamin K deficiency bleeding.



WHAT THIS STUDY ADDS: Refusal of vitamin K is not common, but those who refuse are more likely to have a birth attended by a midwife, and deliver at home or in a birth center. They are also less likely to immunize their child.

abstract

BACKGROUND: Neonatal Vitamin K prophylaxis is an effective intervention for reducing vitamin K deficiency bleeding. A recently published report of parental refusal of vitamin K prompted an investigation of the prevalence and characteristics of this group, and exploration of whether these same parents were likely to subsequently refuse immunization for their children.

METHODS: We conducted a retrospective population-based cohort study of all infants born in Alberta between 2006 and 2012 by using linkage of administrative health data. Risk factors for vitamin K refusal were determined by using Poisson regression. The association between vitamin K refusal and nonimmunization was assessed using relative risk.

RESULTS: Among the 282 378 children in the cohort, 99.7% received vitamin K and 0.3% declined. Midwife-assisted deliveries were more likely to be associated with vitamin K refusal compared with physician-attended delivery (risk ratio 8.4, 95% confidence interval [CI] 6.5–11.0). Planned home delivery (risk ratio 4.9, CI 3.8–6.4) or delivery in a birth center (risk ratio 3.6, CI 2.3–5.6) were more likely to result in decline of vitamin K compared with hospital delivery. Vitamin K refusal was associated with a 14.6 (CI 13.9–15.3) higher relative risk of having no recommended childhood vaccines at 15 months.

CONCLUSIONS: This is the first population-based study to characterize parents who are likely to decline vitamin K for their infants and whose children are likely to be unimmunized. These findings enable earlier identification of high-risk parents and provide an opportunity to enact strategies to increase uptake of vitamin K and childhood immunizations. *Pediatrics* 2014;134:497–503

Vitamin K prophylaxis is an effective and accepted intervention for preventing vitamin K deficiency bleeding (VKDB), a rare bleeding disorder in early infancy that can result in long-term neurologic deficits and death.^{1,2} Neonatal vitamin K is recommended by the American Academy of Pediatrics³ and the Canadian Pediatric Society.⁴ In Canada, vitamin K is typically administered through a single-dose intramuscular (IM) injection at birth, but parents can opt for a multidose oral form administered at birth and over the first few weeks of life.

A recent *Morbidity and Mortality Weekly Report* (MMWR) documented a cluster of 4 cases of VKDB in infants in Tennessee, all among infants whose parents had refused vitamin K prophylaxis.⁵ This report prompted an investigation of vitamin K refusal in our jurisdiction. As the reasons for vitamin K refusal in the MMWR report included concerns about the safety of the medication, we hypothesized that the profile of women refusing vitamin K may be very similar to that of a subset of vaccine-hesitant parents. If true, refusal of vitamin K would allow for early identification of this group for targeted supports and education. The purpose of this study was to determine the prevalence of vitamin K refusal, describe the characteristics of parents refusing vitamin K, and investigate the hypothesis that parents who refuse vitamin K for their newborns are also likely to not immunize their child.

METHODS

Setting

This study was conducted in the province of Alberta, Canada, which has an annual birth cohort of ~50 000 infants. Canada has a publically funded health care system that is administered by the individual provinces. All residents in Alberta are required to register with

the provincial Health Care Insurance Plan, which covers the cost of prenatal care, delivery, postpartum care, and childhood immunizations according to the schedule determined by the Ministry of Health. Residents have a choice of health care provider and expectant mothers with low-risk pregnancies can choose to have an obstetrician, family doctor, or midwife deliver their infant; high-risk pregnancies are delivered by obstetricians. Midwives offer their clients a choice of delivery location, providing services in a hospital, birth center, or at home; physicians routinely deliver in hospitals. Both birth centers and home births have similar limited availability of emergency equipment, and clients must be transferred to a hospital should complications arise. Midwives are a relatively new care provider in the province; they have been registered since 1992 and their services publically funded since 2009.⁶ In 2012, ~1600 (3%) live births in Alberta were delivered by midwives (unpublished Ministry of Health data).

Study Design and Data Sources

We analyzed a population-based cohort of all live births in Alberta between 2006 and 2012 for whom information on vitamin K administration at birth was available ($n = 282\,378$ or 81% of live births in Alberta during the period). Neonatal vitamin K administration is documented on the Notice of Birth (NOB), which captures maternal and infant information on all births that occur in Alberta. The NOB form is completed by health care staff at the birth facilities based on patient charts. Vitamin K prophylaxis is recorded as intramuscular, oral, or “parent declined.” Additional data obtained from the NOB database included site of delivery, primary attendant at birth, maternal age, gestational age, and smoking during pregnancy. We deterministically linked individual-level NOB data to other administrative health databases

by using personal health numbers, which are unique individual identifiers assigned at the time of registration to the Alberta Health Care Insurance Plan. Information on cesarean delivery, administration of epidural during labor, and same or next day admission to the NICU was extracted from the Hospital Discharge Abstract Database.

Data on immunization uptake was obtained from the provincial immunization repository known as ImmARI. ImmARI captures individual-level data on all childhood immunizations administered since 2006, except for First Nations (the largest aboriginal group in Canada) children living on reserve. We linked immunization records of all non-First Nations children in our study cohort who were born between 2006 and 2011 and remained Alberta residents as of 15 months of age. We omitted children born in 2012 from this analysis, as some of them had not yet reached 15 months when the analysis was conducted. The resultant cohort included 214 061 children. According to the recommended childhood immunization schedule, a child 15 months of age would have 3 doses each of DTaP-IPV-Hib (diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type b), meningococcal and pneumococcal conjugate vaccines, and 1 dose each of MMR (measles, mumps, rubella) and varicella vaccines. Assessment of coverage at 15 months of age permitted a 3-month grace period from the time the 12-month immunizations were scheduled. Unimmunized children were defined as those who received no doses of the recommended vaccines.

Statistical Analysis

We determined the uptake of vitamin K prophylaxis in Alberta from 2006 to 2012, and evaluated trends in parental refusal rates during the period using the Cochran-Armitage trend test. We used χ^2 test to examine the association between

vitamin K refusal and maternal and infant characteristics. We estimated the risk ratios of vitamin K refusal by using Poisson regression analysis.

For the 2006 to 2011 non-First Nations birth cohort, we calculated the proportion of children who were unimmunized at 15 months. Relative risk and 95% confidence intervals (CIs) were computed to examine the association between vitamin K refusal and nonimmunization. All data management and statistical analyses were carried out using SAS version 9.3 (SAS Institute, Inc, Cary, NC). A P value $< .05$ was considered statistically significant. Ethical consent for this study was obtained from the University of Alberta Health Research Ethics Board.

RESULTS

Uptake of Vitamin K

The uptake of intramuscular and oral vitamin K prophylaxis in this cohort was 99.3% and 0.4%, respectively (Table 1). Only 0.3% of live births did not receive any vitamin K prophylaxis because of parental refusal. The refusal rate showed a small but statistically significant annual increase over the study period, from 0.21% in 2006 to 0.39% in 2012 ($P < .001$).

Factors Associated With Vitamin K Refusal

Table 2 presents the characteristics of infants and their parents who declined

vitamin K prophylaxis in Alberta. There were significant differences in the uptake of the prophylaxis among birth sites ($P < .001$) and professional groups attending the delivery ($P < .001$). Planned home births had a refusal rate of 14.5%, and births in birth centers had a refusal rate of 10.7%; in contrast, births in hospitals had a refusal rate of 0.2%. Among infants delivered by midwives, 6.8% of parents declined vitamin K prophylaxis; this was higher than those delivered by physicians (0.2%). In addition, vitamin K refusal rates were higher in older, non-First Nations and nonsmoking mothers. Mothers who had a vaginal delivery without the use of epidural during labor had a refusal rate (0.6%) that was higher than mothers who had used epidural for vaginal delivery (0.1%) or mothers who had a cesarean delivery (0.2%). Infants who were born preterm (< 37 weeks) and required admission to the NICU had a slightly higher refusal rate at 0.4%, compared with 0.3% for generally healthy term infants not requiring NICU admission.

The multivariable Poisson regression analyses (Table 3) showed parents who declined vitamin K prophylaxis for their newborns were 8.4 (95% CI 6.5–11.0) times more likely to have a midwife deliver their infants compared with a physician. They were also 4.9 (95% CI 3.8–6.4) times more likely to have a planned home birth and 3.6 (95% CI 2.3–5.6) times more likely to give birth in a birth center compared with a hos-

pital. They were also more likely to be non-First Nations, nonsmoking, and have had a vaginal delivery without the use of epidural. Parents of preterm infants who required NICU admission were more likely to decline vitamin K.

Association Between Vitamin K Refusal and Nonimmunization

Table 4 shows the nonimmunization rates for children receiving and not receiving vitamin K prophylaxis. For DTaP-IPV-Hib, meningococcal conjugate and pneumococcal conjugate, which are scheduled to have 3 doses by 12 months of age, the nonimmunization rates as of 15 months were consistently ~5% in those who received the vitamin K prophylaxis (either injection or oral), but 74% to 75% in those who did not receive vitamin K prophylaxis. For MMR and varicella vaccines, which are scheduled to have 1 dose at 12 months, 18.7% and 20.4%, respectively, of those who received vitamin K prophylaxis were not immunized as of 15 months; in comparison, 82.1% and 85.0%, respectively, were not immunized in those refusing the prophylaxis. Overall, the risk of being completely unimmunized with any of these scheduled childhood immunizations (DTaP-IPV-Hib, meningococcal and pneumococcal conjugates, MMR, and varicella) at 15 months was 14.6 (95% CI 13.9–15.3) times higher in those who declined vitamin K, compared with those receiving the prophylaxis.

DISCUSSION

This study builds on previous research of vitamin K uptake through use of population-based data. Our findings are reassuring in that the overall uptake of vitamin K in this cohort was very high and the prophylaxis continues to be a widespread public health success. However, the small but continuous increase in refusal of vitamin K is cause for concern.

TABLE 1 Uptake and Route of Neonatal Vitamin K Prophylaxis in Alberta, 2006 to 2012

Year	Intramuscular		Oral		Decline	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
2006	37 931	99.39	149	0.39	82	0.21
2007	38 612	99.25	193	0.50	97	0.25
2008	42 567	99.25	190	0.44	133	0.31
2009	39 414	99.26	153	0.39	141	0.36
2010	37 718	99.31	112	0.29	150	0.39
2011	42 350	99.25	185	0.43	137	0.32
2012	41 754	99.26	144	0.34	166	0.39
Total (2006–2012)	280 346	99.28	1126	0.40	906	0.32

TABLE 2 Characteristics of Infants and Their Mothers Who Accepted and Declined Vitamin K Prophylaxis in Alberta, 2006 to 2012

Characteristics	<i>n</i>	IM/Oral Vitamin K, ^a <i>n</i>	(%)	Declined Vitamin K, <i>n</i>	(%)	<i>P</i> Value
Mother's age, y						<.001
<24	61 818	61 683	(99.78)	135	(0.22)	
25–34	175 736	175 137	(99.66)	599	(0.34)	
35+	44 824	44 652	(99.62)	172	(0.38)	
First-time delivery						<.001
No	161 547	160 963	(99.64)	584	(0.36)	
Yes	120 831	120 509	(99.73)	322	(0.27)	
First Nations ^b						<.001
No	261 496	260 612	(99.66)	884	(0.34)	
Yes	20 882	20 860	(99.89)	22	(0.11)	
Site of birth						<.001
Hospital	280 055	279 407	(99.77)	648	(0.23)	
Birth center	224	200	(89.29)	24	(10.71)	
Planned home birth	1486	1270	(85.46)	216	(14.54)	
Others ^c	613	595	(97.06)	18	(2.94)	
Primary attendant at birth						<.001
Physician	272 754	272 212	(99.80)	542	(0.20)	
Midwife	4699	4381	(93.23)	318	(6.77)	
Nurse and others	3090	3046	(98.58)	44	(1.42)	
Delivery						<.001
Vaginal delivery, no epidural	101 329	100 674	(99.35)	655	(0.65)	
Vaginal delivery with epidural	106 565	106 446	(99.89)	119	(0.11)	
Cesarean delivery	74 484	74 352	(99.82)	132	(0.18)	
Infant health status at birth ^d						<.001
Term, no NICU admission	249 059	248 236	(99.67)	823	(0.33)	
Term with NICU admission	17 740	17 707	(99.81)	33	(0.19)	
Preterm, no NICU admission	8571	8552	(99.78)	19	(0.22)	
Preterm with NICU admission	7002	6971	(99.56)	31	(0.44)	
Smoking during pregnancy						<.001
No	223 631	222 799	(99.63)	832	(0.37)	
Yes	48 003	47 954	(99.90)	49	(0.10)	

Missing data: primary attendant at birth (*n* = 1835, 0.6%), infant health (*n* = 6, 0.002%), and maternal smoking (*n* = 10 744, 3.8%).

^a The small number of infants receiving oral vitamin K (*n* = 1126) was combined with those receiving IM vitamin K for this analysis.

^b First Nations: the largest aboriginal group in Canada.

^c Others: primarily unplanned home births, also births occurring en route to hospital (eg, in vehicle).

^d Infant health status: preterm birth (gestational age <37 wk); term (≥37 wk); NICU admission.

Our data did not allow us to determine the reasons why parents were declining vitamin K prophylaxis for their newborns. A possible reason is a lack of/incomplete knowledge of the risks and benefits of the prophylaxis. Our study showed a considerable difference in the uptake of vitamin K between births attended by physicians and those by midwives, even when adjusted for other confounding factors. A recent survey of medical and midwifery attitudes toward vitamin K in New Zealand found that all doctors, but only half of

midwives, believed that all infants should receive vitamin K.⁷ Some midwifery literature suggests that vitamin K may not be necessary for all infants.^{8,9} The perspective or attitude of the health care providers could influence the decision of the parents. It is possible that information presented to midwifery clients on the risks and benefits of vitamin K reflects the controversy in the midwifery literature. This is consistent with the MMWR report that found parental knowledge about late VKDB was absent or incomplete, suggesting

that parental decisions were not well informed.⁵

Factors such as choice of health care provider and place of birth may reflect personal ideologies and growing concerns about the overmedicalization of birth and a preference for a natural birth. Our study showed that mothers who refused vitamin K prophylaxis were more likely to choose a planned birth at home or at a birth center and an epidural-free vaginal delivery. This finding is consistent with the study by Khambalia et al.¹⁰

It is possible that some parents decline vitamin K prophylaxis because of safety concerns. In the 1990s, 2 studies by Golding et al^{11,12} suggested an increased likelihood of childhood cancer with vitamin K intramuscular injection. Although the findings have been refuted subsequently in multiple publications,^{13–15} the legacy of doubt around the injection lingers. This is reminiscent of similar legacies of immunization studies that have been clearly refuted, such as the purported link between MMR vaccine and autism.¹⁶

The finding that women who refuse vitamin K are more likely to have a delivery attended by a midwife highlights opportunities to improve uptake. First, physicians providing preconception care to women intending to seek midwifery care should be aware of the need to provide information about vitamin K. Second, midwives should be engaged, for example by providing guidance documentation on VKDB and vitamin K prophylaxis. There is reason to believe that midwives would be receptive to this; a recent survey found 95% of midwives felt their role was important in providing education/information on vitamin K, compared with 65% for pediatricians and 39% of obstetricians.⁷ Women who have a midwife delivery typically also have received midwifery prenatal care, with the advantage that midwives often can spend a great deal of time with their

TABLE 3 Multivariable Poisson Regression Analysis of Risk Factors for Refusal of Vitamin K Prophylaxis in Alberta, 2006 to 2012

Characteristics	Adjusted Risk Ratio ^a	(95% CI)	P Value
Mother's age, y			
<24	1.02	(0.84–1.25)	.822
25–34	1.00	—	—
35+	1.07	(0.91–1.27)	.419
First-time delivery	0.99	(0.85–1.14)	.842
Non First Nations ^b	2.00	(1.29–3.09)	.002
Site of birth			
Hospital	1.00	—	—
Birth center	3.58	(2.29–5.59)	<.001
Planned home birth	4.92	(3.75–6.44)	<.001
Others ^c	2.12	(1.22–3.67)	.008
Primary attendant at birth			
Physician	1.00	—	—
Midwife	8.43	(6.48–10.96)	<.001
Nurse and others	4.45	(3.11–6.35)	<.001
Delivery			
Vaginal delivery, no epidural	1.00	—	—
Vaginal delivery with epidural	0.33	(0.26–0.41)	<.001
Cesarean delivery	0.52	(0.42–0.64)	<.001
Infant health status at birth ^d			
Term, no NICU admission	1.00	—	—
Term with NICU admission	0.90	(0.63–1.29)	.559
Preterm, no NICU admission	1.05	(0.67–1.66)	.819
Preterm with NICU admission	2.28	(1.58–3.28)	<.001
Not smoking during pregnancy	2.43	(1.80–3.28)	<.001

—, reference group.

^a Adjusted for all variables in the regression model.

^b First Nations: the largest aboriginal group in Canada.

^c Others: primarily unplanned home births, also births occurring en route to hospital (eg, in vehicle).

^d Infant health status: preterm birth (gestational age <37 wk); term (≥37 wk); NICU admission.

clients providing information, as well as answering concerns and misconceptions about the prophylaxis.

We hypothesized that the characteristics of parents who refuse vitamin K may be similar to that of a subset of vaccine-hesitant parents. This group of parents often shares a particular worldview of health that includes a preference for natural health remedies and questions the standard recommended practices of established medical authorities.¹⁷ They are often actively engaged in information-

seeking and decision-making around the health of their child, by using the Internet and alternative health care providers as trusted sources of information.^{17,18} In terms of immunization, this may be expressed by concerns about the necessity, effectiveness, and safety of vaccines.^{19,20} Our results confirm the hypothesis that parents who refused vitamin K were also more likely to have unimmunized children.

A previous survey by Cassell et al²¹ on the factors associated with MMR re-

jection noted that MMR noncompliance was associated with declining vitamin K. Until now, this finding has not been explored further. To the best of our knowledge, this is the first study that used a large population-based cohort to study the association between vitamin K refusal and nonimmunization.

Our finding of vitamin K refusal as a strong predictor of subsequent childhood nonimmunization is important because it allows the opportunity for public health departments and health care providers to identify a subset of parents who are likely to refuse or delay immunization for their child, and provide targeted support and education about the benefits and risks of immunization earlier than would typically occur. There have been recent efforts to develop tools to identify vaccine-hesitant parents based on assessment of their knowledge, attitudes, and beliefs, but the vaccine hesitancy was assessed only once the child was overdue for vaccines.^{22,23} Our finding suggests the possibility of early identification and intervention starting at birth, a time when parents may be most receptive to health information.^{24,25} Strategies might include anticipatory guidance through postpartum home visits by a public health nurse, instead of waiting for the infant's first encounter with the medical system or until the first immunization is missed. Another strategy is to engage the midwife to promote immunization, as women choosing a midwife delivery continue to receive midwifery care until 6 weeks after delivery.

TABLE 4 Proportion and Relative Risk of Being Unimmunized at 15 Months Among Those Who Received or Declined Vitamin K, 2006 to 2011

Vaccine	Number (%) Unimmunized Among Those Who Received Vitamin K, n = 213 373	Number (%) Unimmunized Among Those Who Declined Vitamin K, n = 688	Relative Risk (95% CI) of Being Unimmunized
DTaP-IPV-Hib	11 151 (5.23)	508 (73.84)	14.13 (13.47–14.82)
Meningococcal	11 630 (5.45)	518 (75.29)	13.81 (13.19–14.47)
Pneumococcal	11 759 (5.51)	519 (75.44)	13.69 (13.07–14.33)
MMR	39 808 (18.66)	565 (82.12)	4.40 (4.25–4.56)
Varicella	43 505 (20.39)	585 (85.03)	4.17 (4.04–4.31)
All of above vaccines	10 744 (5.04)	505 (73.40)	14.58 (13.89–15.30)

Strengths of this study include the use of a population-based design, which minimizes selection bias, and the linkage of multiple population-based registries, which enables a more complete description of maternal and infant characteristics. The potential for bias does exist given that data on vitamin K prophylaxis was not available on 19% of live births in our cohort. However, there is no reason to suggest that the missing status was dependent on vitamin K status, as most missing NOB forms were associated with reporting from certain geographic regions. It is possible that our findings may not be generalizable to regions where midwifery care is the standard of care or where vitamin K administration practices differ. This study showed that parental refusal of vitamin K prophylaxis is strongly associated with subsequent nonimmunization, but does not distinguish between parental choice and other

barriers preventing uptake of immunization.

CONCLUSIONS

This study found that parents who refused vitamin K prophylaxis for their newborns are more likely to have a planned midwifery delivery at home or in a birth center, have an epidural-free vaginal delivery, and be less likely to smoke during pregnancy. They were also more likely to not immunize their child. This study provides objective criteria for identifying parents who are likely to refuse vitamin K for their infants and who are likely to have unimmunized children.

These findings have important clinical and public health implications. First, it highlights the need for physicians to provide anticipatory guidance on the benefits of vitamin K to parents who are

planning home birth or a midwife-attended delivery. Second, it points to an opportunity to engage midwives so that education about the risks and benefits of vitamin K prophylaxis can begin before birth among a population group that is likely to decline prophylaxis. Third, it provides an opportunity to identify a subset of vaccine-hesitant parents who are likely to not immunize their children, and engage them with targeted education starting at birth instead of waiting until the scheduled immunizations are missed. Targeting this population earlier, and with a provider with whom a trusted relationship has already been developed, may help increase coverage rates.

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MODERATE IS IN THE EYE OF THE BEHOLDER: *I visited friends in Boston last weekend. The weather was perfect, so we decided to go for a bicycle ride. As we had not previously cycled together, we spent more than a few minutes trying to decide how fast and far to ride. My two friends stated that they had been exercising quite a bit and that a moderate ride should be easy. After a mile, however, it became quite clear that the three of us had very different visions of what moderate exercise meant.*

As reported in The New York Times (Well: June 11, 2014), adults are not very good at judging the intensity of their workouts. Canadian and United States guidelines suggest that adults complete 150 minutes of moderate or 75 minutes of vigorous aerobic exercise each week. Moderate and vigorous exercise is often defined by the level of sustained elevation in heart rate as a percentage of maximum heart rate. Canadian researchers asked sedentary adults to review national exercise guidelines and, after establishing that the participants understood the guidelines and what was meant by moderate and vigorous exercise, measured their maximum heart rate on a treadmill test. Participants were then asked to walk or jog at a pace the individual thought as moderate or vigorous and then later at the slowest pace that would be considered moderate.

Unfortunately, a minority of adults actually met heart rate changes consistent with moderate exercise, and very few met the heart rate changes associated with vigorous exercise. More strikingly, only about one-quarter of participants accurately judged a pace that was at least consistent with moderate exercise. The implications are that many adults are overestimating the intensity of their exercise, and that they may not be getting as much benefit from exercise as expected. Either the guidelines need to be a bit clearer or individuals, such as my friends, need to be more honest about how much effort they have put into their exercise routine.

Noted by WVR, MD

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